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No. 85-1470

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

COMMUNITY NUTRITION INSTITUTE, ET AL.,
Petitioners,

v.

FRANK E. YOUNG, COMMISSIONER OF FOOD AND DRUGS,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR RESPONDENT THE NUTRASWEET COMPANY

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QUESTION PRESENTED FOR REVIEW

Whether the court of appeals properly affirmed the Food and Drug Administration's decision that aspartame is safe for use in carbonated beverages and that Petitioners had failed to raise any genuine and substantial issues of fact justifying a hearing.

PARTIES TO THE PROCEEDING

In addition to the parties listed by Petitioners in their petition for a writ of certiorari, The NutraSweet Company (NutraSweet), respondent/intervenor in the court of appeals, is a respondent in this Court.[1] Sup. Ct. R. 19.6.

1. In January 1986, G.D. Searle & Co., intervenor below, changed its name to The NutraSweet Company. Another company called G.D. Searle & Co. has been formed, which company has no interest in aspartame. Both NutraSweet and G.D. Searle & Co. are wholly owned subsidiaries of Monsanto Company.

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BRIEF FOR RESPONDENT THE NUTRASWEET COMPANY

The Respondent, The NutraSweet Company, respectfully requests that this Court deny the petition for a writ of certiorari seeking to review the opinion of the United States Court of Appeals for the District of Columbia Circuit reported at 773 F.2d 1356.

STATEMENT

Petitioners challenge the Food and Drug Administration's (FDA's) approval of aspartame for use in carbonated beverages. The approval of aspartame has followed a long path through a painstaking review process at the FDA and in the courts. Aspartame was originally approved in 1974 for certain "dry uses," such as in cold breakfast cereal, chewing gum, and beverage mixes. *See* 21 C.F.R. § 172.804(c). After that approval, two objectors, including counsel for Petitioners in this case, requested and received a hearing before the FDA. Ultimately, in July 1981, aspartame was finally approved for dry uses. That decision was not appealed. (Pet. App. 3a).

In October 1982, NutraSweet petitioned FDA to expand the approved uses of aspartame to include carbonated beverages.

After evaluating the scientific evidence submitted by NutraSweet, FDA decided to approve aspartame for the carbonated beverage use.

After *Federal Register* publication of the approval by FDA, Petitioners, including Petitioners' counsel, filed objections with FDA and requested a hearing. (Pet. App. 7a). After a lengthy and careful evaluation of the objections, FDA, on February 22, 1984, denied the objections and request for a hearing because Petitioners failed to raise any genuine or substantial issues of fact. (Pet. App. 7a). In so doing FDA stated that "[a]spartame has been exhaustively tested for safety and the data have been reviewed by the agency over the course of 11 years .... The safety testing conducted for aspartame surpasses the testing requirements for direct food additives developed by the agency...." (Pet. App. 61a-62a).

The court of appeals agreed with FDA. In particular, the court noted that many of the issues raised by Petitioners had previously been decided by FDA in the course of the dry use hearing and that therefore those issues could not be relitigated by Petitioners in the absence of "new evidence suggesting that reliance on those issues in the context of wet use is erroneous." (Pet. App. 16a). With respect to the other objections raised by Petitioners, that is, that aspartame may have an embryotoxic effect and that it decomposes at high temperatures, the court found "no evidence on either of these points that would require the FDA to hold a hearing." (Pet. App. 21a). No food product has ever been so closely examined for safety, and the decisions of the agency have been given the fullest airing that the legal process requires.

ARGUMENT

The court of appeals correctly noted that Petitioners have ignored that the statute does not automatically entitle one to a hearing. The Federal Food, Drug, and Cosmetic Act provides that a request for a hearing and objections to a food additive regulation must specify with particularity the provisions of the

order deemed objectionable and state reasonable grounds for the objections. 21 U.S.C. § 348(f). A hearing is to be held for the purpose of receiving evidence relevant and material to the issues raised by the objections. If there are no genuine and substantial issues of fact to be resolved at a hearing, FDA should not be required to provide Petitioners such a hearing. *Pineapple Growers Association of Hawaii* v. *Food and Drug Administration*, 673 F.2d 1083, 1085 (9th Cir. 1982).

FDA in its regulations has articulated fully the bases for granting of a hearing, requiring the presentation of "a detailed description and analysis of the factual information to be presented in support of the objection." 21 C.F.R. § 12.22(a)(5). These regulations provide that hearings will not be granted on issues of policy or law, 21 C.F.R. § 12.24(b)(1), or on the basis of "mere allegations or denials or general descriptions of positions and contentions." 21 C.F.R. § 12.24(b)(2). Moreover, a hearing will be denied if "the data and information submitted are insufficient to justify the factual determination urged, even if accurate." 21 C.F.R. § 12.24(b)(3). A hearing will also be denied if a factual issue, even if resolved in favor of the objector, will not change the FDA's decision; that is, if it is immaterial. 21 C.F.R. § 12.24(b)(4).

Having failed to raise a genuine and substantial issue of fact, Petitioners contend that the court below has shifted the burden to them to prove not only the existence of a genuine issue of fact but that they would prevail on such an issue prior to granting a hearing.

Petitioners have misread the opinion of the court of appeals in this case. The court of appeals did not, as Petitioners contend, require them to "prove the addition of aspartame to carbonated beverages unsafe." (Pet. 7). All that the court required that Petitioners do was demonstrate that a genuine and substantial issue of fact existed to justify a hearing, and that they present new evidence in order to be able to relitigate issues that were already resolved in the earlier dry use proceeding.

To support their specious argument that the court of appeals has shifted the burden to them to prove that aspartame is unsafe, Petitioners quote portions of the court's opinion out of context. A reading of the opinion below, however, demonstrates that there was a careful analysis of the Petitioners' objections to determine whether any of them met the standard of raising a genuine and substantial issue of fact. Petitioners cite four instances in which the court below is said to have required them to prove aspartame unsafe. An examination of those four cited instances reveals the unsoundness of Petitioners' contentions.

1. Petitioners claim that the court of appeals found that evidence cited by them failed "to demonstrate that . . . biochemical changes produced behavioral changes." (Pet. 5). On this issue, the court found that assertions about potential behavioral effects amounted to no more than mere speculation. Speculation, of course, does not raise a material issue and is insufficient under FDA's regulations to warrant a hearing. 21 C.F.R. § 12.24(b)(2). Petitioners offered no evidence that the alleged biochemical changes produced any behavioral changes, or would produce behavioral changes, in humans or animals.

2. Concerning the issue of carcinogenicity, Petitioners quote the court as saying that "the Commissioner concluded . . . that aspartame had not been *shown to cause* cancer . . ." (Pet. 5). The quotation ignores the court's analysis that the carcinogenicity study at issue was carefully reviewed in the earlier dry use proceeding, and that the Petitioners were unable to cite any specific deficiencies in that study that came to light after the dry use proceeding which would entitle them to relitigate the carcinogenicity issue.

3. On the issue of potential embryotoxic effects, Petitioners misuse the language of the court of appeals to contend that they were required to prove embryotoxic effects. Neither the quoted language nor the context within which the language was written supports such a conclusion. The court did note that the Petitioners sought to prove such effects, and that Petitioners had cited a letter from a Dr. Jean Lederer as the basis for their allegation.

(Pet. App. 21a). The court also noted appropriately that the record showed that Dr. Lederer could not associate any fetal damage with aspartame. (Pet. App. 21a). The court therefore found that FDA could not be faulted for concluding that Petitioners had not raised a material issue.

4. Petitioners raise the issue of consumer complaints, which they introduced in the district court proceeding to support their application for an order requiring FDA to hold a hearing. The language quoted by Petitioners—that FDA found "no pattern of complaints that would indicate that aspartame was *unsafe* . . ." (Pet. 5)—is unrelated to the review of the agency approval of aspartame for wet use. Rather, that language is simply the court of appeals' description of the filing made by FDA in the district court proceeding. (Pet. App. 8a).

The Petitioners' forceful attack on a standard that the court of appeals palpably did *not* use provides an insufficient basis for this Court to assert its discretionary power of review.

As another ground for their petition for certiorari, Petitioners state that they are entitled to a hearing on the issue of labeling for aspartame. (Pet. 8). Petitioners contend that FDA agreed to consider labeling at the dry use hearing and then refused to do so. This is of course an issue which, if it had any merit, should have been appealed from in the dry use proceeding. Moreover, the court of appeals properly noted that in the dry use proceeding, there was consideration of " . . . the issue of appropriate warnings." (Pet. App. 20a-21a). The court determined that Petitioners' "current objections do not present any new evidence or suggest any material issue of fact about the necessity of additional warning or labeling requirements." (Pet. App. 21a).

Finally, Petitioners seriously misstate the nature of the food additive approval process, claiming that it is a "closed dialogue" between FDA and the petitioner for the additive, and that other interested persons are not provided the "opportunity to present their knowledge, information and expertise in the food safety decision" until after the product has been approved (Pet. 6). This is simply wrong. When a food additive petition is filed, FDA

is required to publish in the *Federal Register* a notice of filing of the petition within 30 days. 21 U.S.C. § 348(b)(5).

FDA's regulations provide that at the time of such filing, unless extraordinary circumstances are shown, most of the information in the petition is available for public disclosure, including "all safety and functionality data," "a protocol for a test or study," and "adverse reaction reports, product experience reports, consumer complaints, and other similar data and information." 21 C.F.R. § 171.1(h). Although FDA does not specifically solicit comments on the petition at the time it publishes a notice of filing in the *Federal Register*, there is nothing to prevent an interested person from submitting comments. Indeed, in the aspartame carbonated beverage proceeding, a number of comments were submitted, some technically after the comment time had passed, and FDA responded to them in the preamble to the final regulation. (Pet. App. 26a). Interested parties, therefore, have an opportunity to participate in the food additive approval process prior to publication of a final rule. In the case of aspartame, Petitioners had the opportunity to participate fully in the approval process; they simply dislike the result.

CONCLUSION

The issues raised by this proceeding have been properly resolved by the court of appeals. The decision of the court of appeals is correct and does not conflict with the decisions of this Court or any other court of appeals. Further review by this Court is not warranted. The petition for a writ of certiorari should therefore be denied.

Respectfully submitted,

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